U.S.S.N.: 10/691,928 Filed: October 23, 2003 AMENDMENT FURTHER TO SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

1. (currently amended) A topical antifungal composition comprising:

- a) a therapeutically effective amount of an antifungal compound for treating a fungal disease or a pharmaceutically acceptable salt thereof; and
- b) a therapeutically effective amount of a low to low-medium potency steroidal antiinflammatory causing minimal skin atrophy, striae and hypopigmentation, in a concentration between 0.01 wt% and 5.0 wt%, and having a higher potency than 1 wt% hydrocortisone, and
- c) a carrier suitable for administration of the antifungal compound and the steroidal antiinflammatory to the skin, wherein the composition does not cause the steroids to penetrate the skin and cause undesirable side effects.
- (previously presented) The antifungal composition of claim 1 wherein the steroidal antiinflammatory has the following structure:

wherein R₁, R₂, R₃, and R₄ taken independently can be H, C1-C10 alkyl, C1-C10 alkenyl, C3-C10 cycloalkyl, and phenyl groups; R₁ and R₂ taken together can be C3-C10 cycloalkyl; and R₃

U.S.S.N.: 10/691,928

October 23, 2003 AMENDMENT FURTHER TO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

and R4 taken independently can be H, C1-C10 alkyl, C1-C10 alkenyl, C3-C10 cycloalkyl,

phenyl, C7-C10 phenylalkyl, carboxylate, sulfonyl, phosphoryl, and phosphonyl groups.

3. (previously presented) The composition of claim 1 wherein R₁, R₂, R₃, and R₄

groups are independently H, CH3, ethyl, propyl, phenyl, and phenylmethyl groups.

(previously presented) The composition of claim 2 wherein the steroidal anti-4.

inflammatory is desonide and the antifungal compound is clotrimazole.

(original) The composition of claim 4 containing 0.01 wt % to 5.0% wt % 5.

desonide.

(original) The composition of claim 5 containing 0.1 wt % to 5 wt %

6 clotrimazole.

> (previously presented) The composition of claim 1 wherein the steroidal anti-7.

inflammatory is selected from the group consisting of Fluocinolone acetonide, Hydrocortisone

valerate, Hydrocortisone butyrate, Alclometasone dipropionate, Desonide, and hy drocortisone

probutate.

8 (original) The composition of claim 1 wherein the antifungal is selected from the

group consisting of polyene type antifungal agents and azole type antifungal agents.

(original) The composition of claim 8 wherein the antifungal is selected from the 9.

group consisting of Amphoterican B, Nystatin, Flucytosin, Natamycin, Ketoconazole,

Econoazole, Miconazole, Itraconazole, Fluconazole, Econazole, Clotrimazole, Griseofulvin,

Oxiconazole, Terconazole, Tioconazole, Clotrimazole, Silver Sulfadiazine, Ciclopirox olamine,

and Terbinafine.

3

JAG 100 092687/00002 U.S.S.N.: 10/691.928

Filed: October 23, 2003 AMENDMENT FURTHER TO SUPPLEMENTAL INFORMATION

DISCLOSURE STATEMENT

10. (original) The composition of claim 1, wherein the composition is formulated as

a cream, ointment, gel, lotion, foam, powder, aerosol, spray, shampoo, or liquid solution.

(original) The composition of claim 10 having a pH of about 3.5 to about 7.0

further comprising: at least one solvent, at least one emollient, at least one humectant, at least

one preservative, and at least one emulsifier; and optionally including an acid, base, or buffering

agent to adjust the pH.

12. (original) The composition of claim 11, wherein the solvent is selected from the

group consisting of propylene glycol, butylene glycol, hexylene glycol, polyethylene glycols,

polypropylene glycols, and polyurethane compounds; the emollient is selected from the group

consisting of white petrolatum, mineral oil, propylene glycol dicaprylate, lower fatty acid esters

and lower alkyl ethers of propylene glycol, cetyl alcohol, cetostearyl alcohol, stearyl alcohol,

stearic acid, cetyl esters wax, spermaceti wax, and white wax; the humectant is selected from the

group consisting of glycerin and sorbitol; and the emulsifier is selected from the group consisting

of glyceryl monostearate, glyceryl monoleate, stearic acid, polyoxyethylene cetyl ether,

polyoxyethylene cetostearyl ether, polyoxyethylene stearyl ether, and polyethylene glycol

stearate; wherein the optional acid is selected from the group consisting of hydrochloric acid and

phosphoric acid, the optional base is chosen from diethanolamine, triethanolamine, and sodium

hydroxide, the optional buffering agent is chosen from monobasic sodium phosphate and dibasic

sodium phosphate, and the preservative is chosen from benzyl alcohol, sodium benzoate and

parabens.

4

JAG 100 092687/00002 U.S.S.N.: 10/691,928 Filed: October 23, 2003

AMENDMENT FURTHER TO SUPPLEMENTAL INFORMATION

DISCLOSURE STATEMENT

13. (original) The composition of claim 1 wherein the antifungal is in an amount

 $effective \ to \ treat \ fungal \ disease \ selected \ from \ the \ group \ consisting \ of \ tinea \ pedis, \ tinea \ capitis,$

tinea corporis, tinea versicolor, scalp disorders, tinea cruris, and candidiasis.

14. (previously presented) A method of treating a fungal disease comprising

administering to a subject in need of treatment the composition of any of claim 1-13 or 17, with a

thin application of the composition two times per day to the affected areas.

15. (original) The method of claim 14 wherein the subject is a child of under 10 years

old.

16. (original) The method of claim 14 wherein the fungal disease is selected from the

group consisting of tinea pedis, tinea capitis, tinea corporis, tinea versicolor, scalp disorders,

tinea cruris, and candidiasis.

17. (previously presented) The composition of claim 1 wherein the steroidal anti-

inflammatory is not halogenated.

5

JAG 100 092687/00002